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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/826,843 | 04/15/2004 | Robert T. Lyons | 17684 (AP) | 2070 |

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03/24/2005

Brent A. Johnson
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,843

Applicant(s)

LYONS ET AL.

Examiner

Zohreh Fay

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Art Unit: 1614

Claims 1- 25 are presented for examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1, 2, 4-10, 15, 18-24 are rejected under 35 U.S.C. 102 (b) as being anticipated by Lipari (U.S. Patent 4,383,992). Lipari teaches the use of a beta-cyclodextrin in an ophthalmic formulation in combination with prednisolone acetate and hydroxypropylmethylcellulose at the claimed concentrations. See example 2. the above reference also teaches the increased solubility of the steroids by the addition of cyclodextrin. See column 2, lines 23-35.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 11, 12, 14, 16, 17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipari (U.S. Patent 4,383,992) and Loftsson (U.S. Patent 4,383,992).

Lipari teaches the use a beta-cyclodextrin in an ophthalmic formulation in combination with prednisolone acetate and hydroxypropylmethylcellulose in an ophthalmic formulation. See example 2. The above reference also teaches the increases solubility of steroids by the addition of cyclodextrin. The above reference differs from the claimed invention in the concentrations of hydroxypropylmethylcellusoe and the use of hydroxypropylbeta-cyclodextrin and gamma-cyclodextrin. Loftsson

Art Unit: 1614

teaches that hydroxypropylbeta-cyclodextrin and gamma cyclodextrin have been previously used in an ophthalmic formulation in combination with steroids and many other active ingredients in an ophthalmic formulation. See claims 74, 76, 83 and 94. Loftsson also teaches that the addition of cyclodextrin to a drug results to fast and effective drug release, increased solubility and stability. See column 1, lines 10-22. It would have been obvious to a person skilled in the art to incorporate a hydroxypropyl-beta-cyclodextrin and a gamma-cyclodextrin into the teachings of the primary reference considering that the secondary reference teaches the addition of such agents to ophthalmic compositions as old and well known. The secondary reference also teaches the concentrations of hydroxypropylmethyl cellulose as claimed herein.

One skilled in the art would have been motivated to combine the teachings of the above references, since they in combination relate to the use of different types of cyclodextrin in ophthalmic formulations. The above references, in combination make clear that the use of different types of cyclodextrin in ophthalmic formulations for increase drug release, stability and solubility is old and well known. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 3, 11, 12, 14, 16, 17 and 25 are properly rejected under 35 U.S. C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

Art Unit: 1614

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

